

**GLOVE PACKAGE, UNPACKING DEVICE THEREFOR, AND GLOVE
DONNING SYSTEM**

Technical Field

The present invention relates primarily to an improved glove package and a device for unpacking the gloves from such a package. The present invention also relates to donning systems that incorporate such a device to facilitate the donning of gloves in an automatic manner such that the user or wearer is not required to manually grasp the gloves during the donning operation. Such donning systems are particularly advantageous for donning surgical gloves and also for donning gloves used in clean rooms in the semiconductor/microprocessor and pharmaceutical industries where avoidance of contamination of gloves is of the highest priority.

Background

The importance of donning surgical gloves or gloves used in semiconductor "clean rooms" in a contamination-free manner is well known. The presence of microbial contaminants on the gloves, arising from manual manipulation of the gloves during donning, for example, can have adverse and even lethal effects on a patient undertaking surgery. Similarly, particulate contaminants passed on from a glove can destroy a semiconductor wafer.

Surgeons' gloves, patient examination gloves, and other medical gloves are intended to provide an effective barrier against potentially infectious materials and other contaminants. However, the use of such gloves has been associated with a number of adverse health effects in patients and users, including allergic reactions, foreign body reactions and irritation. Natural rubber latex (NRL), from which such gloves are generally made, comprises a variety of naturally occurring substances, including plant proteins, which are believed to be the primary allergens associated with natural latex allergy. Nonetheless, NRL gloves provide users with great sensitivity and no suitable synthetic replacement is currently available. However, NRL gloves are difficult to don and doff, and thus glove powder, which comprises cornstarch as a main component thereof, is often used for lubricating the inside surfaces of the gloves. Natural latex allergens are known to bind to cornstarch, and thus the use of donning powder may pose an additional hazard for allergic personnel and patients. Recently, FDA has received requests to ban the use of all powdered glove, due to the indications that cornstarch on surgical gloves can reduce tissue resistance to infection, enhance the development of infection and act as a carrier of natural latex protein from NRL products, for example [Federal Register: July 30, 1999 (Volume 64, Number 146) Proposed Rules, Page 41709-41743 from the Federal Register Online via GPO Access (wais.access.gpo.gov), 21 CFR Parts 801, 878, and 880]. In June 1997, the National Institute of Occupational Safety and Health (NIOSH) of the US issued a safety alert recommending the use of powder-free, reduced protein content or synthetic gloves as a means to reduce exposure to natural latex

allergens, specifically via the airborne route of exposure [Department of Health and Human Services (NIOSH), "National Institute of Occupational Safety and Health (NIOSH) Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace", Publ. No. 97-135, June 1997.]. While the FDA agrees with the goal of reducing exposure to airborne allergens, it is at the same time concerned that efforts to produce powder-free gloves with satisfactory donning properties may require additional manufacturing processes that, if not appropriately controlled, have deleterious effects on physical properties, performance and shelf-life of the gloves [Aziz, N., "Chlorination of Gloves" Paper No. 5. of the Latex Protein Workshop of the International Rubber Technology Conference, June 1993, Kuala Lumpur, Malaysia; FDA, CDRH, "Environmental Degradation of Latex Gloves: The Effects of Elevated Temperature on Tensile Strength", Division of Mechanics and Materials Science Report # 96-05, D. Walsh, D. Chwirut, R. Kotz, and J. Dawson, Rockville, MD, 1997]. In fact, the FDA is encouraging industry to find a balance between donning requirements -hitherto met by use of the powder - and reducing the risk of adverse health effects.

Rather than using donning powder, lubrication of the gloves may be provided, instead, by a coating or by chlorination. Various kinds of coating are in use. Their manufacture, like the chlorination process, must be carefully controlled. Since the coatings may have different physical properties from that of the NRL glove, they may not generally have the same stretching characteristics, and thus provide a different "feel" to a user than regular NRL gloves. Furthermore,

such coatings add costs to the price of the gloves, particularly for damp hand donning.

Chlorination is widely used for reducing the tackiness of natural latex gloves and thus eliminates the need for donning powder. Chlorination works by degrading the surface of the gloves, and thus the chlorination process must be very carefully controlled to prevent destruction of the glove barrier. Improperly chlorinated gloves rapidly degrade, and breaks in the latex film may occur within a span of a few months.

An alternative approach to using less effective synthetic gloves, or to providing NRL gloves with less or alternative forms of lubrication to donning powder, is to provide a glove donning system that reduces the need for lubrication. Such a donning system would thus enable regular NRL gloves (as well as any similar type of glove) to be donned without lubrication, in particular donning powder, by elastically deforming the inside of the glove to a volume greater than the hand of the user. In particular, such a system requires the cuff of the glove to be elastically expanded to a size such as to facilitate insertion of a hand therethrough and into the body of the glove.

Glove donning systems are known, for example, in US 3,695,493, US 4,002,276, US 4,275,812, US 4,069,913, US 4,155,494, US 5,058,785, US 5,078,308, US 4,915,272, US 4,889,266, US 4,228,935 and US 4,898,309.

In particular, WO 01/89406 provides an improved automatic glove donning system, which comprises a glove grasping means, typically a vacuum wand,

adapted to grasp the outer skin of the cuff portion of a glove. The system also comprises means for transporting the glove into a vacuum chamber such that the cuff portion of the glove is more-or-less aligned with the perimeter or rim of the opening of the vacuum chamber. By grasping only the outer skin of the glove, the cuff portion is gently opened sufficiently to enable an inflatable ring to be inserted into the cuff portion in the deflated state. The ring is then inflated while positioned inside the cuff portion so that the cuff portion is stretched and expanded until it touches the rim of the vacuum chamber. The rim is provided with a suction ring capable of generating sufficient suction to keep the cuff of the glove pressed against the rim, at which point the inflatable ring may be deflated and removed with the grasping means. With the glove thus held within the vacuum chamber, a vacuum is applied to the chamber inflating the glove and thus enabling a hand to be inserted into the glove.

The system of WO 01/89406 may further comprise a glove magazine having a stacked arrangement of sterilised and/or contamination-free gloves, in which the gloves are all oriented in substantially the same manner, typically in a flattened state with the upper part of the glove (corresponding to the back of the hand) being substantially parallel and in close proximity to the lower part of the glove (corresponding to the palm area). The gloves are elastically expandable, or at least the cuff portions of the gloves are elastically expandable, and are provided in a non-expanded condition. The magazine is adapted for presenting an uppermost glove of a stack of gloves at a particular height within the housing and thus comprises any suitable elevator

mechanism to push the stack upwards by a suitable amount whenever the uppermost glove is removed. When the stack of gloves in the magazine is exhausted, a new stack of gloves may be inserted therein from the storage chambers in a contamination free manner.

While sterile gloves are available, typically double packed in pairs, the packaging configurations known in the art are not compatible with the glove donning system of WO 01/89406.

It is therefore an aim of the present invention to provide a glove package and an unpacking system or device therefor which overcomes the aforementioned limitations of glove donning systems.

It is another aim of the present invention to provide a glove package and an unpacking system or device for facilitating the provision of gloves to a glove donning system in a substantially contamination free manner.

It is another aim of the present invention to provide such a device or system that is simple to use.

It is another aim of the present invention to provide such a system that is relatively simple mechanically and thus economic to produce as well as to maintain.

Summary of Invention

According to the present invention, an alternative and improved solution is provided to that of the glove stack of WO 01/89406. According to the present invention, gloves, and particularly pairs of gloves, are provided in pre-packed packages, which may be opened in sterile conditions when required for use in the donning system.

According to the invention, a glove package is provided for at least one glove, and preferably for a pair of gloves, comprising:-

- an outer hermetically sealed envelope openable under preset conditions; said outer envelope enclosing

- an inner envelope comprising a first inner sheet and a second inner sheet in substantial overlying relationship, said first inner sheet having one longitudinal free edge in overlying relationship with a free longitudinal edge of said second inner sheet;

- at least one glove disposed between said first inner sheet and said second inner sheet, wherein a cuff portion of said at least one glove is substantially aligned with said free edges of said first inner sheet and said second inner sheet; and

- suitable grasping means – including apertures on the inner envelope and/or tabs that project from the inner sheets and into the cuff portions - for enabling each of opposed sides of said cuff portion in proximity to said first inner sheet and said second inner sheet, respectively, to be held firmly with respect to said first inner sheet and

said second inner sheet, respectively, at least during a part of a preset unpacking procedure of said package.

Such packages would reduce potential problems associated with the stack, and moreover would also reduce the need for such magazines, and therefore enable the overall dimensions of the donning system to be reduced.

The packages according to the present invention may also be used in the regular manual manner, in which the cuff portions are folded back to enable the same to be grasped manually and donned over the hands while holding only the inner surface of the gloves.

The present invention is also directed to a glove unpacking apparatus, comprising, inter alia,

separating means for holding said first sheet and said second sheet in said housing while said separating said first inner sheet from said second inner sheet such as to open the said cuff portion of said gloves;

a housing having an inlet opening and an outlet opening;

conveying means for conveying a said glove package from said inlet opening to said separating means;

opening means for holding and opening said cuff portion of said cuffs after said first sheet is separated from said second sheet;

cuff expansion means capable of being reversibly expanded from a first configuration that is sufficiently compact such as to be introduced into said cuff portion, to a second configuration sufficiently expanded such as to abut with respect to and expand said cuff portion;

removing means for at least partially removing the first outer sheet from the second outer sheet and for introducing said inner envelope into said housing via said inlet opening.

The present invention also relates to a glove donning system comprising housing accommodating:-

a glove unpacking apparatus;

at least one vacuum chamber and preferably a pair of vacuum chambers operatively connected to a vacuum source, said vacuum chamber comprising cuff holding means comprising suction means and at least one suitable contact surface for sealingly holding a cuff portion of a glove in an open condition when said cuff portion is in abutting contact with said at least one surface; and

first transport means for transporting said at least one glove from said unpacking apparatus to said at least one vacuum chamber.

Description of Figures

Figure 1 illustrates in general isometric view the general components of a first embodiment of the glove package of the present invention.

Figure 2 illustrates in general isometric view the general components of a second embodiment of the glove package of the present invention.

Figure 3(a) illustrates in longitudinal cross-sectional view the general components of a third embodiment of the glove package of the present invention; Figure 3(b) illustrates a transverse cross section taken along P-P in Figure 3(a); Figures 3(c) and 3(d) illustrates some details of the tab of Figures 3(a) and 3(b).

Figures 4(a) and 4(b) illustrate in transverse cross-sectional view a first embodiment of the unpacking apparatus of the present invention, receiving an inner envelope, and holding the same, respectively; and Figure 4(c) illustrates in orthogonal transverse cross-sectional view this embodiment wherein the upper and lower sheets of the inner envelope are separated to open the cuff portion.

Figure 5 illustrates in sectional view the embodiment of Figure 4 taken along X-X, illustrating the operation of the mechanical holding means.

Figures 6(a) and 6(b) illustrate in isometric view a preferred embodiment of the mechanical holding means of the present invention.

Figures 7(a), 7(b) and 7(c) illustrates in cross-sectional view the embodiment of Figure 4(a) and 4(b), further comprising feeding means for feeding the inner envelope into the housing in various operational configurations.

Figures 8(a) and 8(b) illustrate in cross-sectional view the embodiment of Figure 5, wherein a deflated balloon of a cuff expansion system is introduced into the opened cuff, and wherein the balloon is partially inflated, respectively.

Figures 9(a) and 9(b) illustrate in transverse cross-sectional view a second embodiment of the unpacking apparatus of the present invention, receiving an inner envelope and holding the same, respectively.

Figures 10(a) and 10(b) illustrate in cross-sectional view the embodiment of Figures 9(a) and 9(b) taken along Y-Y, wherein Figure 10(a) illustrates the upper and lower sides of a glove cuff portion being separated via a suitable probe means, and wherein Figure 10(b) illustrates a cuff expansion system opening the cuff portion;

Figure 10(c) illustrates along another cross-section of this embodiment, wherein the probe means partially inflates the glove that is previously grasped by the cuff expansion means.

Figure 11 illustrates in front elevational cross-sectional view, a preferred embodiment of the system for donning gloves according to the present invention.

Figure 12 illustrates, in transverse cross-section view, the embodiment of Figure 11.

Figures 13(a) to 13(e) illustrate in partial transverse cross-sectional view, the embodiment of Figures 11 and 12 at various stages of operation.

Disclosure of Invention

The present invention is defined by the claims, the contents of which are to be read as included within the disclosure of the specification, and will now be described by way of example with reference to the accompanying Figures.

The present invention relates to a glove package particularly adapted for enabling the same to be opened in a sterile and automated manner, and such as to facilitate the entry of a cuff expansion means, typically in the form of an inflatable balloon of any suitable shape.

For the purposes of the description, relative terms may be used for ease of comprehension thereof, including "upper", "lower", "vertical", "horizontal", "side", and so on. These terms are not to be considered as limiting in any way the present invention.

The term "cuff portion" is herein taken to refer to the open portion of the glove through which the user inserts the hand in order to don the glove, whether or

not the free edge of the glove has been turned inside out to expose part of the inside of the glove.

Referring to Figure 1, a first embodiment of the package of the present invention, generally designated at (100), comprises an outer envelope (110), commonly known as a "pouch", which is hermitically sealed so as to prevent contamination of the contents thereof. The outer envelope is typically made from an upper sheet (112) and a lower sheet (114) of suitable material and of general rectangular plan form, superposed and heat sealed or otherwise sealingly joined at the edges thereof, which include two parallel longitudinal edges (116) joined at their extremities to a leading edge (117) and a trailing edge (118), after the contents have been introduced. The edges, in particular the leading edge (117) and the longitudinal edges (116) are adapted for separating the upper sheet (112) from the lower sheet (114), when a predetermined separating force is applied thereto, and the trailing edge (118) is preferably sealed in a more permanent fashion, as will be understood more clearly below. Thus, preferably, the upper sheet (112) and lower sheet (114) are not fully bonded at the leading edge (117), but rather the longitudinal extremities or free ends (113) of these sheets are not separated, as illustrated in Figure 1. Preferably, the free ends (113) are folded back to facilitate the grasping of these ends (113) mechanically, as will be further described herein. Nevertheless, there is sufficient bonding between the upper sheet (112) and the lower sheet (114) at the leading edge to hermetically insulate the inner envelope (200) from the external environment and thus from possible

contamination from particles and/or biological agents. Typically, the outer envelope is made from paper, plastic or any other suitable sheet material, and preferably contains printed data, including manufacturer name, country of origin, opening instructions, batch number, expiry date and so on.

Inside the outer envelope (110) there is an inner open package or envelope (200), which is commonly known as the wrapper or the wrapping paper , comprising a pair of gloves (150), in juxtaposed arrangement. In some embodiments, the glove package may only comprise a single glove, and are thus similar to those described herein with respect to a pair of gloves, mutatis mutandis. Preferably, the gloves (150) are each provided in a substantially flattened condition, and folded over itself over the remaining portion of the glove in juxtaposition. For example, the gloves may be folded about the wrist part thereof, or alternatively at the knuckles, so that the finger portions fold over the thumb portion, for example. Preferably, a part of the cuff portion of each glove is folded backwards and inside out over itself such that a part of the inner surface of the cuff portion is now exposed on the outside. These configurations minimise the size and volume of each package (100).

The inner envelope (200) comprises an upper sheet (212) and a lower sheet (214) of suitable material and typically of general rectangular plan form, and superposed in overlying relationship. The inner envelope (200) comprises a trailing edge (220) and a leading edge (240) at opposite longitudinal ends thereof, as illustrated in Figure 1. The upper sheet (212) and a lower sheet (214) are joined together at least at the trailing edge (220) thereof;

alternatively, the upper sheet (212) and a lower sheet (214) are made from one piece of sheet material folded over at the trailing edge (220). Optionally, the inner envelope may be made integrally as a continuous unit. Typically, the inner envelope (200) is made from paper, for example 45g/square meter, although it may be made from any suitable sheet material. While circumscribing the upper and lower flattened surfaces of the adjacent pair of gloves (150), the inner envelope (200) is nevertheless open at least on one side (260) thereof such as to expose the cuffs (155) of the gloves (150).

The inner envelope (200) is particularly characterized in comprising suitable grasping means in the form of tongue elements or tabs (250) that project into each of the cuffs (155) of the gloves from the upper sheet (212) and lower sheet (214) from the respective longitudinal edges (215) thereof. The tabs (250) may be integrally formed with the upper sheet (212) and the lower sheet (214). Alternatively, the tabs (250) may be suitably bonded or otherwise joined to the upper sheet (212) and the lower sheet (214). Each pair of tabs (250) for any one glove (150) has the function of maintaining separated at least the cuff portion of the upper and lower flattened glove sides (160), (170), respectively, at least during a predetermined part of the unpacking procedure. Thus, the tabs (250) are advantageously formed as hook-like projections that penetrate into the glove (150) from the lateral edges (262), (264) of the open side (260). The tabs (250) may be made from the same material as the upper sheet (212) and lower sheet (214), and formed integrally therewith. Alternatively, the tabs (250) may be made from any other suitable materials. Alternatively, the tabs (250) may

be made as separate parts, to be bonded or otherwise joined to the inner envelope (200) in an appropriate manner.

The inner envelope (200) is also characterized in being adapted for enabling the upper sheet (212) to be separated from the lower sheet (214) in a substantially vertical manner, without introducing significant longitudinal displacement to the inner envelope (200) itself or to the gloves (150) therein. The reason for this will become apparent hereinbelow. In the preferred embodiment, the inner envelope (200) comprises an expansion region (245) in the form of an accordion-like multiplicity of alternating folds of the sheet material at or near the leading edge (240) thereof. Similarly, expansion region (225) also in the form of an accordion-like multiplicity of alternating folds of the sheet material may be provided at or near the trailing edge (220) thereof. In the preferred embodiment, the trailing edge (220) is longitudinally spaced from the trailing expansion region (225) by a stub region (230), which generally comprises a portion of the upper sheet (212) and a portion of the lower sheet (214) extending from the expansion region (225) to the trailing edge (220). In practice, the trailing expansion region (225) and the leading expansion region (245) may be integrally formed with either one or both of the upper sheet (212) and the lower sheet (214), or suitably joined thereto. Thus, the expansion regions (225), (245) may be made from the same material as the upper sheet (212) and lower sheet (214), optionally integrally with one or the other or both. Alternatively, the expansion regions (225), (245) may be made from the same or different materials and bonded or joined in any suitable way

to the upper sheet (212) and lower sheet (214). In other embodiments the upper and lower sheets may be joined directly without the expansion regions, and the dimensions of the glove are generally sufficient for allowing the upper and lower sheets to be slightly separated without significantly disturbing the gloves therein.

Referring to Figure 2, a second embodiment of the package according to the present invention, designated herein as (100'), comprises all the elements and features of the first embodiment as described herein, *mutatis mutandis*, with the following differences. In the second embodiment, the corresponding inner envelope (200') comprises a plurality of holes (201) on the upper sheet (212) and lower sheet (214), such as to expose and thus provide communication between the upper side (160) and the lower side (170) of the gloves, respectively, and the outside of the upper sheet (212) and lower sheet (214), respectively. Further, the tabs (250) are optional and not strictly required.

Referring to Figures 3(a), 3(b) and 3(c), a third embodiment of the package according to the present invention, designated herein as (100''), comprises all the elements and features of the first embodiment or of the second embodiment as described herein, *mutatis mutandis*, with the following differences. In the third embodiment, the gloves are preferably packed with the free edge (258) of the cuff portion of each glove folded backwards over the rest of the cuff portion such that the inner surface of a part of the cuff portion is now on the outside (though optionally they may also be packed with the cuff portion unfolded). In particular, and as illustrated in Figure 3(c) and Figure 3(d), a first part (251'')

of the tabs (250") may comprise adhesive or is otherwise bonded to the upper sheet (212), or in fact may also be integrally formed therewith. A second part (252") of the tabs (250") that abuts or is in contact with the inside of the glove comprises adhesive zones (253"), comprising a very weak adhesive, either in continuous form or alternatively in non-continuous form such as in the form of one or more strips or spots,. These adhesive zones (253") help to hold the glove in place during transportation and handling of the packages. On the other hand, the amount and/or strength of adhesive in the adhesive zones (253") are insufficient to prevent the glove from being removed from the package manually or with the system of the invention.

In the embodiments described herein, the stub region (230) may be formed as an extension of the upper sheet (212) or of the lower sheet (214), as illustrated in Figures 1, 3, and Figure 2, respectively.

While the package (100, 100', 100") of the present invention is advantageously used with an unpacking apparatus or to a glove donning system according to the present invention such as that described herein, it may also be used for manually donning gloves in a more sterile manner than prior art gloves. For example, the user may open the outer envelope, and then grasp the cuffs by holding the tabs (250) and the upper sheet (212) or lower sheet (214) to manually open the cuff portion, and then force the hands therethrough, particularly with the first or third embodiments of the package (100), (100").

The present invention also relates to a glove package unpacking apparatus and to a glove donning system which may advantageously incorporate said unpacking apparatus. The unpacking apparatus may also be used without reference to the donning system. In any case, the unpacking device of the present invention enables the glove package of the present invention to be unpacked in a sterile and automated manner, and is also used in the donning system of the invention by presenting the gloves ready for additional manipulation for the donning thereof.

Referring to the figures, Figures 4(a), 4(b) schematically illustrate a first and preferred embodiment of the glove unpacking apparatus (300), comprising a housing (305) having a closeable entry port or inlet opening (310) for inserting the pair of gloves at least in the inner package thereof, and a closeable outlet opening (320) (see Figure 5) for removing each glove for donning thereof. The inlet opening (310) is typically in orthogonal arrangement with respect to the outlet port (320). The apparatus is adapted for use with glove packages according to the present invention, and is described herein in the first instance in relation to the first embodiment of the glove package (100) operation of the apparatus with respect to the other embodiments of the glove packages is similar, *mutatis mutandis*. The apparatus may be used on its own to enable a user to unpack the glove package in a sterile or clean manner, so that the user may then manually don the gloves via outlet (320). Advantageously, though, the apparatus (300) is preferably adapted for use with the glove donning system of the present invention herein, as will be described further herein.

The unpacking apparatus (300) may be mounted onto a floor, table or wall, or alternatively onto a trolley or wheeled cart to be easily transportable from one location to another. The apparatus (300) optionally comprises one or a plurality of storage chambers (not shown) for storing sterilised and/or contamination-free packages (100) of gloves ready to be unpacked by the apparatus and used thereafter.

A lower table (410) is provided inside the housing (305) for receiving the inner envelope (200) of a glove package (100), after the outer envelope (110) has been substantially removed therefrom, as will be described in greater detail hereinbelow. The lower table (410) is typically aligned with the lower edge of inlet opening (310), or arranged below the same, and comprises suction means preferably in the form of a plurality of apertures (415) on the upper surface of the table (410) which are in communication with a vacuum source (not shown) via suitable ducting. When the vacuum source is actuated, a suction force is applied to the lower sheet (214) of the inner envelope (200), holding the lower sheet in place over the lower table (410).

The housing (305) also accommodates a suitable actuation or driving device, typically in the form of an upper piston (420) reciprocally movable towards and away from the lower table (410). The piston (420) comprises a suction pad (430) at the lower end thereof that comprises suction means in the form of a plurality of apertures (435) on the lower surface thereof in communication with a vacuum source (not shown), which may be the same source as that of the lower table (410) or alternatively different thereto, via suitable ducting. The

size of the upper pad (430), and the disposition of apertures thereon, is such as to superpose at least a significant portion of the upper sheet (212). When this vacuum source is actuated, a suction force is applied to the upper sheet (212) of the inner envelope (200), holding the upper sheet in place in abutment with the pad (430).

When the inner envelope is first inserted into the device (300), the piston (420) is slightly retracted, providing an upper clearance between the pad (430) and the inner envelope (200), as illustrated in Figure 4(a). After the first vacuum source has been actuated, so that the lower sheet (214) is held onto the table (410) by suction, the piston (420) extends until contact is established between the pad (430) and the upper sheet (212). Then the second vacuum source is actuated, whereupon the upper sheet is held against the pad (430), as illustrated in Figure 4(b).

Referring to Figure 4(c), the piston (420) is then retracted in an upwards direction, lifting with it the upper sheet (212) away from the lower sheet (214). The expansion regions (225) and (245) allow for this movement without creating shear forces between the upper sheet (212) and the pad (430), or between the lower sheet (214) and the table (410). At the same time, since the tabs (250) are holding the cuff portion of the upper and lower sides of the gloves (150) in place with respect to the upper sheet (212) and lower sheet (214), respectively, the upper side (160) of each of the gloves (150) is similarly separated and distanced from the corresponding lower side (170), thereby opening the cuff (155) to some extent.

Optionally, the table (410) may also be operatively connected to another actuation or driving device, such as a piston, such that both the pad (410) and the table (430) reciprocally move towards and away from each other.

Alternatively, the table and pad arrangement may be inverted, with the pad below and the table above.

Preferably, the apparatus (300) further comprises mechanical opening means for holding and opening the cuffs (155) of the gloves (150) prior to a subsequent operation, typically the insertion of a deflated balloon thereinto, as will be described in more detail herein or alternatively the manual grasping of the cuff portion by a user.

Referring to Figures 4(c) and 5, the mechanical opening means (590) according to one embodiment comprises a pair of pusher plates (520), one each mounted orthogonally to the end of a rod (525). Each rod (525) is adapted for reversibly moving from a retracted position clear of the opening (320) and the inner envelope (200), to a deployed position, in which the end of the rods carrying the pusher plates (520) are inserted into the cuff portion (155) of the gloves (150) when this has been slightly opened as illustrated in Figure 4(c). The pusher plates (520) are oriented such as to be substantially coplanar with the table (410) or pad (430) and facing one another when they are inserted into the cuff portion (150). Thus the pusher plates (520) are aligned with the slit opening provided between the upper side (160) and the lower side (170) when the pad (430) is retracted upwards as illustrated in Figure 4(c). The rods (525) may

then be urged downwards slightly to press onto the lower side (170) of the glove, and thus clamp this mechanically against the table (410) via the lower sheet (214). Thereafter, the rods (525) are rotated in opposite directions about their longitudinal axis, so that the plates (520) rotate from a horizontal to a vertical position. In the process the cuff portion (155) is opened and the upper side (160) is distanced from the lower side (170) of the glove (150) thereat, as illustrated in Figure 5, all the time the end of the rods (525) clamping down on the lower side (170).

In a preferred embodiment, and referring to Figures 6(a) and 6(b), the mechanical opening means (600) comprise a pair of probes (610), each of which is adapted for reversibly moving from a retracted position clear of the opening (320) and the inner envelope (200), to a deployed position, in which the end of the probes (610) are inserted into the cuff portion (155) of the gloves (150) when this has been slightly opened as illustrated in Figure 4(c), *mutatis mutandis*. Each pair of probes is adapted for distancing the individual probes therein one from the other such as to hold and stretch said cuff portion. The probes (610) are thus advantageously in the form of rods, typically but not limited to a diameter of about 1.5cm and open to, i.e., separate from each other by, up to about 16 cm, each having a leading edge (615) which is thus preferably rounded for facilitating insertion into the cuff portion (155) of the glove (150), which has already been slightly opened by means of the pad (430) and table (410) arrangement (shown as phantom lines in these figures. The probes (610) are carried on a platform (650) which may be transported towards

and away from the cuff portion (155) by means of transportation means (660). Such transportation means (660) may comprise, for example, a suitable jack or piston arrangement, conveyor or pulley arrangement or indeed any other suitable propulsive arrangement, powered by any suitable means including but not restricted to electrical, hydraulic or pneumatic, that may provide the desired displacement with respect to the gloves. The platform (650) also comprises a suitable displacement mechanism (670) that enables the probes to reversibly move away from each other, and again such a mechanism (670) may include any jack, piston, conveyor or pulley arrangement or indeed any other suitable propulsive arrangement, powered by any suitable means including but not restricted to electrical, hydraulic or pneumatic, that may provide the desired displacement with respect to the gloves.

Operation of the system (600) is as follows. The probes (610) are aligned with the slit opening provided between the upper side (160) and the lower side (170) when the pad (430) is retracted upwards as illustrated in Figure 4(c), *mutatis mutandis*. Referring to Figure 6(a), the probes (610) are then inserted into the middle of this slit via mechanism (660), and then the probes are distanced from each other by means of the mechanism (670), such as to abut and slightly stretch the cuff (155) at each end of the slit opening, thereby clamping the cuff (155), as illustrated in Figure 6(b). As will become clearer herein, after the gloves (150) are held by the cuff expansion means, the probes (610) may be retracted away from the cuff portions (155) via any suitable movement, typically provided by the mechanism (670).

Referring to Figures 7(a), 7(b) and 7(c), the apparatus (300) comprises an envelope handling mechanism (550) externally to said inlet opening (310). The inlet opening (310) is typically in the form of a horizontal slit, comprising a door such as a flap (551) that closes the opening (310) when not in use. The handling mechanism (550) comprises a pair of rollers (552) disposed one above and one below the inlet opening, and close to the casing (305). The rollers (552) have friction inducing surfaces or surface features, and are coupled to a suitable motor (not shown) for providing rotation to the rollers in opposed directions one from the other. A substantially horizontal support (555) is provided for resting the package (100) substantially in alignment with the opening (310).

When it is desired to insert a package (100, 100', 100'') of gloves into said apparatus (300), the leading edge of the outer envelope (110) is opened, either manually, by holding the free ends of the leading edge (117) and pulling the ends in opposite directions, or mechanically to achieve the same effect. The upper sheet (112) is separated from the lower sheet (114) thereat sufficiently so as to pass upwards the separated part of the upper sheet (112) between the upper roller (552) and the side (306) of the casing (305) on which the inlet opening (310) is located. At the same time, the separated part of the lower sheet (114) is passed downwards between the lower roller (552) and the side (306). When the rollers (552) are suitably counter-rotated, they urge the separated parts of the upper sheet (112) and lower sheet (114) away from each

other, thereby separating the two sheets, and advancing the inner envelope (200) into the casing (305) via the inlet opening (310).

Preferably, the rollers are controlled to limit the rotation such that a trailing edge (118) portion of the outer envelope (110) remains outside the casing (305). The stub region (260) of the inner envelope (200) is preferably of sufficient size such that at least a part thereof remains outside of the casing (305) with the trailing edge (118) while the rest of the inner envelope is positioned over the table (410). The actuating mechanism for the rollers (552) are further adapted to enable the rollers to be reversibly displaced at least towards each other so as to clamp the trailing edge (118), and also the stub region (230), onto the support (555), as illustrated in Figure 7(b). For this purpose, the rollers (552) may be eccentrically mounted to a support in a suitable manner. This provides additional mechanical stability to the inner envelope (200) during the subsequent pre-donning procedure.

Any other suitable envelope handling mechanism may be employed, according to the specific structure of the outer envelope of the package.

The casing (305) is preferably over-pressurised using clean air, i.e., the casing (305) is provided with air pressure greater than the ambient pressure, to ensure sterility or cleanliness of the environment within the casing while a package is being inserted therein.

As illustrated in Figure 8(a) and Figure 8(b), preferably, a cuff expansion system (500), typically in the form of an inflatable ring or balloon (510) of any

suitable shape, is now introduced in the deflated state into the cuff portion of one of the gloves via the outlet opening (320). This procedure is considerably facilitated by the previous step of mechanically opening and maintaining the cuff (155) in the open position via opening means (590) or (600). Typically, the balloons (510) comprise a flattened configuration when deflated in order to facilitate their introduction into the cuff portion (155).

The balloon (155) is then inflated sufficiently such as to hold firmly the cuff section. Typically, the balloons (510) comprise a shape having a substantially circular periphery when partially or fully inflated. The upper pad (430) may also be lifted, and the balloon of the cuff expansion system (300) is retracted from the apparatus (300), removing with it the glove (150). The glove (150) may then be taken via suitable transport means to a vacuum chamber (not shown) having a suction ring at the mouth thereof, as described for example herein, and the balloon further inflated until the expanded cuff portion abuts against the suction ring. Once the cuff portion (150) is properly positioned in such a manner, a vacuum is applied to the ring, and this now holds the expanded cuff portion (150) firmly against the ring, in a similar manner to that described below in the context of the system of the invention, *mutatis mutandis*. The balloon may then be partially or fully deflated and removed from the cuff portion, and returned to the apparatus (300) to procure the second glove (150). In the meantime, suction is applied to the vacuum chamber, which serves to fully open the glove, after which it may be donned by

the user. Alternatively, two cuff expansion systems may be employed in tandem or juxtaposition for simultaneously procuring both gloves.

After the two gloves have been procured by the cuff expansion system (500) and placed in the respective vacuum chambers, or indeed as soon as the gloves have been removed from the inner envelope (200), the rollers counter-rotate, thereby urging the upper sheet (112) and the lower sheet (114) in the opposite direction to before, pulling the inner envelope (200) (minus the gloves) out of the casing (305), and enabling the safe and easy disposal of the inner and outer used envelopes simultaneously.

Operation of the apparatus (300), with or without the mechanical holding means (590) or (600), with respect to the second embodiment of the package (100') is similar to that described above with respect to the first embodiment of the package (100), mutatis mutandis, with the following differences. When unpacking the second embodiment of the glove package (100') and the inner envelope (200') is inserted into the apparatus (300) in a similar manner to that shown in Figure 4(a), 4(b) and 4(c), the vacuum source(s) are activated for the pad (430) and the table (410). The upper side (160) and lower side (170) of the gloves (150) are directly acted upon by the suction forces via the holes (201) on the inner envelope (200'), enabling the glove sides to be firmly held against the pad (430) and table (410). Thus, when the pad (430) is lifted as illustrated in Figure 4(c) for the first embodiment, the sides (160), (170) are separated, enabling the deflated balloon of the cuff expansion system (500), directly or preceded by the mechanical holding means (590) or (600), to be inserted into

the space created between the sides. Thereafter, the operation continues in a similar manner to that described with respect to the first embodiment of the glove package (100), *mutatis mutandis*.

Referring to Figure 9(a), a second embodiment of the unpacking apparatus, herein designated (300'), comprises all the elements as described herein for the first embodiment of the apparatus (300), *mutatis mutandis*, with the following differences. In the second embodiment, the piston (420') comprises a smaller pad (430') than in the first embodiment, and no suction is induced thereat. Rather, and as illustrated in Figure 9(b), when the inner envelope (200) is introduced into the housing (305) and is resting over the suction table (410), the piston (420') extends downwards and the pad (430') mechanically holds the upper sheet (212) in place, using any suitable mechanical grasping or holding means. As in the first embodiment, the table (410) holds the lower sheet (214) via suction.

For the second embodiment, and referring particularly to Figure 10(a) and 10(b), the cuff expansion system (500) comprises a suitable probe means (560) extending downstream of inflatable ring or balloon (565) thereof, similar to that as described in WO 01/89406, *mutatis mutandis*. The probe means (560) has a head (561) comprising at least one nozzle means for directing pressurised gas in a downstream direction. The nozzle means are preferably in the form of a plurality of radial apertures, and the probe means (560) further comprises a compressed gas line in communication with said probe head, said pressurised gas line being connectable to a suitable pressurised gas source. The probe head

(561) preferably comprises a relatively narrow transverse profile with respect to the transverse profile of ring or balloon (565) when this is deflated. The probe head (561) is adapted to be insertable in-between the substantially flattened opposed sides (160), (170) of the said cuff portion (155). The said probe means (560) is capable of providing compressed gas flow into the glove (150) when at least said head (561) is inserted the said cuff portion (155). The compressed gas flow provided by said head (561) is at least sufficient to separate said opposed flattened sides (160, (170) to enable said deflated ring or balloon (565) to be inserted into said cuff portion (155). Thereafter, as illustrated in Figure 10(b), the balloon (565) is inflated sufficiently such as to partially stretch and hold the cuff portion (155), whereupon the piston (420') is retracted, and the glove (150) may removed as before.

Advantageously, prior to removing the glove (150), the probe means (560) continues to supply pressurized gas or air into the glove after the balloon (565) holds the cuff portion (155). This has the effect of partially inflating the glove, as illustrated in Figure 10(c), and thereby enabling its maneuver to the vacuum chambers to be more easily controlled and reducing the possibility of the (deflated) glove from interfering with the suction rings of the vacuum chambers during insertion therein.

Thus, the probe means (560) may also be advantageously incorporated into the first embodiment of the apparatus (300) in a similar manner to that described for the second embodiment, *mutatis mutandis*.

Referring to Figures 11 to 13(e), a preferred embodiment of donning system of the present invention, generally designated (900), comprises a housing (990) having an upper portion (991) accommodating: a glove unpacking apparatus (910); an envelope handling mechanism (930); mechanical opening means (940); cuff expansion system (950) and vacuum chambers (960). A pair of openings (998) is provided on the upper part for enabling the user to introduce the hands into the gloves, when these have been prepared for donning, as will become clearer below. Hermetically sealable doors (993) are provided to maintain the inside of the housing sterile and/or contamination free.

Referring particularly to Figures 11 and 12, the housing (990) preferably comprises a suitable filter (999) on upper portion (991) thereof, to filter particles and/or bacteria from entering the housing (990). Preferably, the filter is a 0.2 micron Hepa filter. Preferably, at least the upper part (991), and optionally all the housing (990) is kept pressurized at a gauge pressure slightly above atmospheric, so as to prevent entry of particles and/or bacteria and particles thereinto.

The lower portion (992) of the housing (990) comprises at least one magazine (920) which provides a glove package on demand to the glove unpacking apparatus (910). The user steps on a pedal (921) or other interface to choose a glove of the required size from the magazine (920). In one form thereof, the magazine is in the form of a turntable having its turning axis aligned horizontally, and comprising, for example, eight compartments (923) along the periphery thereof, which may be used to store glove packages. The

compartments (923) are open at both longitudinal ends thereof. Advantageously, the compartments (923) are each used to store similar-sized gloves. Suitable propulsion means (not shown) such as a motor, for example, provide rotational motion to the turntable until the glove package compartment (923) of appropriate size is at the top. When required, the glove package in the uppermost compartment is pushed out via a suitable mechanism such as a piston arrangement (925), and onto a waiting platform (926). The platform (926) may be elevated by any suitable means, such as lift (927), into a sub-chamber (939) in the upper portion (991), until the package is aligned with the inlet opening (931) to the unpacking apparatus (910).

In a similar manner to that described herein regarding the glove unpacking apparatus (300), *mutatis mutandis*, the package is first pushed towards the opening (931) by suitable means such as a piston arrangement (936), and the outer envelope (110) is then peeled off the inner envelope (200) by means of rollers (932), which after the gloves have been removed from the inner envelope (200), counter-rotate and extract the inner envelope (200) and outer envelope (110) from the unpacking apparatus (910) and discard the empty package into a receptacle (935) via a trap-door arrangement, for example. Where only the upper portion (991) is pressurized to a pressure above atmospheric, this zone is effectively insulated from the sub-chamber (939) and the lower portion (992), enabling the magazine (920) to be resupplied, and the receptacle (935) emptied, without fear of contamination of the upper part (991). Whenever desired or necessary, the receptacle may be removed from the

housing (900) via a suitable opening (not shown). Any other suitable arrangement may be employed, alternatively, for removing the outer envelope from the inner envelope.

As with the unpacking apparatus (300) described above, the unpacking apparatus (910) of the system (900) comprises an upper pad (911) and a lower table (912), which essentially sandwich the package between them, and then provide a vacuum to the upper and lower portions of the inner envelope (200) such as to separate them. In the unpacking apparatus (910) of the system (900) the upper part (991) serves a similar function to the housing (305) of the unpacking apparatus (300) described above. Preferably, both the pad (911) and table (912) reciprocally move towards each other, but it is also possible for either one of these components to remain stationary, and the reciprocal movement to be effected by the other component. Thus, the pad (911) and/or table (912) are mounted on a suitable actuation mechanism (913) to provide the required vertical movement.

Once the inner envelope (200) has been parted, the mechanical opening means (940) are engaged with each of the gloves (150), by first inserting into the corresponding cuffs (155) a pair of probes (941) and distancing the probes therein such as to stretch the cuffs (150) via suitable mechanism (942). This enables a mechanical hold to be maintained on each glove (150). Thus, the mechanical opening means (940) may be similar to the mechanical opening means (590) or (600) described above. At this point, the mechanism (942) may be used to retract the mechanical opening means (940) away from the inner

envelope (200), thereby removing the gloves (150) therefrom. After this, the inner envelope is ejected from the glove unpacking means (910), as described herein.

The vacuum chambers (960) are each connected to a suitable vacuum source (not shown), and each comprise a suction ring (961), substantially as described in WO 01/089406, the contents of which are incorporated herein in their entirety, for holding thereat the cuff portion of the glove by suction when the cuff is expanded and in abutment therewith, as will be described herein. Thus, the suction rings (961) typically comprise suction means, connected to a suitable vacuum source, and at least one suitable contact surface (964), when the cuff portion (155) is suitably expanded to contact peripherally this surface.

The vacuum chambers (960) are transversely separated one from the other by a distance typically such as to facilitate the eventual donning of the gloves. The vacuum chambers (960) comprise an axial opening (965) for enabling the gloves to be donned, but also have a lower opening (966), which is sealable and reversibly openable via doors (967). While the vacuum chambers (960) are typically cylindrical, they may be of any suitable shape. The vacuum chambers (960) are mounted onto a suitable transportation means (969), such as rails, pulleys, jacks or the like, for example, to enable the vacuum chambers (960) to be moved from a retracted position for receiving the gloves (150) to a donning position in which the gloves may be donned by the user, as will be further explained below.

Referring particularly to Figure 13(a), in the next stage of the donning process, that is, after the mechanical holding means (940) are holding the gloves (150) with the cuffs (155) open, the lower opening (966) is opened, and the mechanism (942) displaces the mechanical opening means (940) into juxtaposition with the openings, typically such that each glove is directly under one or other of the openings (966). Prior to this, a suitable mechanism reversibly moves the unpacking apparatus (910) out of the way. Then, the mechanism (942) elevates each one of the mechanical opening means (940) together with their corresponding gloves (150) into the corresponding cylinder (630) into a substantially axial position such that the cuff (155) of each glove (150) faces the axial opening (965).

The cuff expansion system (950) typically comprise a pair of reversibly inflatable rings or balloons (951), in communication with a suitable compressed gas or air supply), and coupled to a suitable mechanism (952) that provides the required displacements to the balloons (951), as will become clearer herein. The balloons (951) preferably also each comprise at least one air probe and nozzle (not shown) at the leading edge thereof, in communication with a suitable compressed gas or air supply (not shown). The mechanism (952) is generally maintained in a parked position above (or possibly below) the vacuum chambers (960). Referring to Figures 13(a) and 13(b), after the mechanical opening means (940) together with their corresponding gloves (150) have been introduced into the vacuum chambers (960), the mechanism (952) axially aligns each balloon (951) with its corresponding vacuum chamber

(960), and then displaces the balloons into the axial openings (965) of the vacuum chambers (960) such as to introduce the leading edge and a substantial portion of each balloon (together with its air nozzles) into the cuff portion (155) of the corresponding glove (150), held open and in alignment via the mechanical opening means (940). The balloons are partially inflated, sufficiently such as to hold the cuff portions firmly, and the mechanical opening means (940) are retracted away from the gloves (150), and moved back to their parking position to await their next glove package. Air (or a suitable gas) is then introduced into the glove via the probe and nozzles (not shown), partially inflating the gloves to assume a substantially axially aligned configuration, and thereby preventing the gloves (150) from fouling with the bottom opening (966). The bottom opening (966) is then sealingly closed via doors (967) (which may be configured as part of the cylindrical shell (968) of the vacuum chambers (960). Referring to Figure 13 (c), the mechanism (952) is configured to then partially retract the balloons (951), which are holding the gloves (150) to the openings (965) of the vacuum chambers (960), such that in each case a part of the cuff portion (155) is aligned axially with the suction ring (961). More air or gas is then provided to the balloons (951) to inflate them sufficiently so as to make contact between the cuff portions (155) and the inner periphery or contact surface (964) of the suction rings (961), whereupon suction is provided to the suction rings from a suitable source to hold the cuff portions (155) firmly in place. The cuff expansion system (950) is further adapted to deflate the balloons (951) at this point, and the mechanism (952) retracts the

deflated balloons (951) from the gloves (150) and to its parked position, away from the vacuum chambers (960).

In the next stage of the process, and referring to Figure 13(d) in particular, a vacuum is applied to the vacuum chambers (960), and thus to the outer surface of the gloves (150), causing the gloves (150) to expand and effectively inflate within the chambers (960), while being firmly held at the cuff portions (155) via the rings (961) due to the greater pressure acting on the inside of the glove. At this point, the displacement mechanism (969) moves the vacuum chambers (960) from the retracted or parked position showed in Figure 13(d) or Figure 12, for example, towards the housing (999) to the donning position illustrated in Figure 13(e), such that the axial openings (965) of the chambers (960) are aligned and abutted against corresponding openings (998) in the housing (999). Sealing means (997), such as o-rings for example, are provided on the rings (961) and/or the openings (998) to prevent entry of external air into the housing (999) when the doors (993) are opened. Typically, the doors (993) remain closed even after the gloves have been prepared for donning, and await a further signal or activity, such as pressing a foot pedal switch, for example, or getting close to a proximity sensor, for example, by the user to open the doors. Thus, in case the user is delayed in donning the gloves for some reason, the risk of contaminating the housing or gloves is minimized. When the user opens the doors (993) and introduces the hands into the gloves, the suction ring (961) is deactivated, and the vacuum in the vacuum chambers (960) is turned off, enabling the cuff portion to close onto the user's wrists or lower

arms. The user can then finish the donning manually by unfolding the exposed cuff portion over the lower arms. Preferably, the suction ring is deactivated in response to a signal or action from the user, so that this only happens when the user has fully inserted all the fingers into the gloves. Alternatively, the suction ring (961) may be deactivated automatically, either by means of a time delay, or suitable sensors that sense that the fingers have fully been introduced.

Concurrent with terminating the action of the suction rings (961), a suitable purging gas – such as air, for example - at over pressure is introduced into the vacuum chambers (960) via suitable means (not shown) until a little after the doors (993) have been hermitically closed with respect to openings (998). In this manner, the sterility and cleanliness of the vacuum chambers (960) is ensured while they are being exposed to the outside environment.

Each step in the donning process for the donning system (900), and indeed each step in the unpacking process for the unpacking apparatus (300) may be controlled using any computer means, or alternatively using a suitable electronic control system, or may be configured mechanically or in any other suitable manner to synchronise all the above steps.

While the donning system (900) has been described above as relating to the simultaneous donning of a pair of gloves, the donning system may be instead modified to enable only one glove to be donned at a time, in a similar manner as described above, *mutatis mutandis*. Alternatively, the system (900) may

also be modified to enable more than one user to don gloves simultaneously or pseudo simultaneously. For example, the housing may comprise two or more pairs of vacuum chambers, each pair of which enables a user to don gloves independently of other users. In such a system, a common or separate glove unpacking systems may be used for unpacking the glove packages. Similarly, a common or separate mechanical opening means may be used for manipulating the gloves into the vacuum chambers. Similarly, a common cuff expansion system, or alternatively a plurality of separate cuff expansion systems, may be used for the different pairs of vacuum chambers. In all donning systems, optionally more than one magazine (920) may be provided, of the turntable or other type, for increasing the capacity of the system and/or for giving the user greater choice.

While in the foregoing description describes in detail only a few specific embodiments of the invention, it will be understood by those skilled in the art that the invention is not limited thereto and that other variations in form and details may be possible without departing from the scope and spirit of the invention herein disclosed.